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EXAMINER

LAYNO, C

ART UNIT

PAPER NUMBER

3737

DATE MAILED:

04/03/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/101,723

Applicant(s)

BEN-HAIM et al

Examiner

CARL H. LAYNO

Group Art Unit

3737

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 2/15/00.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-60 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 16, 17, 24, 25, 46, 47, And 52-57 is/are allowed.
- ☒ Claim(s) 1, 2, 4, 7-9, 11, 12, 14, 18-23, 26, 27, 30, 32, 35-37, 39-43, 44, 45, 49, 51 is/are rejected.
- ☒ Claim(s) 3, 5, 6, 10, 13, 15, 28, 29, 31, 33, 34, 38, 43, 48, 50, And 58-60 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The proposed drawing correction, filed on 2/15/00 is ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

1. Acknowledgment is made of applicant's amendment and 3-month extension of time which were received by the Office on February 15, 2000. These documents have been made of record in the file as Paper Nos.8 and 7, respectively.

#### ***Information Disclosure Statement***

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on February 15, 2000. This document has been made of record in the file as part of Paper No.7.

#### ***Drawings***

3. The corrected Fig.4B was received by the Office on February 15, 2000. This corrected drawing is approved by the Examiner.

4. In view of applicant's modifications to Fig.4B to show implantable light sources and waveguides, the Examiner is withdrawing the 37 CFR 1.83(a) objection against the drawings which was made in the last Office Action.

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***Specification***

5. In view of the applicant's submission of an Abstract and corrections to the specification, the Examiner is withdrawing the objections which were made against the specification in the last Office action.

***Claim Objections***

6. In view of applicant's numerous modifications to the claims, the Examiner is withdrawing the objections which were made against claims 11, 13-15, and 43-45 in the last Office action.

***Claim Rejections - 35 USC § 112***

7. Upon further reconsideration of applicant's recitation of support in the specification for the features of a "light source" having a specific frequency range and a "means of irradiating", the Examiner is withdrawing the 35 U.S.C 112 1st paragraph rejection which was made in the previous Office action.

8. In view of applicant's many modifications to the claims, the Examiner is withdrawing the 35 U.S.C 112 2nd paragraph rejections which were made against claims 1-26, 28-45, 47-51, and 58 in the last Office action.

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*Claim Rejections - 35 USC § 102*

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

10. Claims 1, 2, 4, 7-9, 11, 12, 14, 18, 20-23, 30, 32, 35-37, 39-42, 44, 49, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Kieval '464 (applicant's prior art).

The Kieval '464 patent, submitted by the applicant as prior art, describes an implantable cardiac stimulation device whose use reads upon applicant's claimed method of modifying heart activity. In use, the Kieval device 700 (Fig.9) supplies an electric field through patch electrodes 706,708 (Figs.9, 10, 13, 14). The electrodes provide an Anodal Stimulation (AS) pulse at a time between cardiac depolarization pulses (Fig.2B-- graphs f and a) where it is unable to generate an action potential (col.4, lines 34-35). These AS pulses optimize cardiac output by maintaining adequate blood pressure in the right ventricle (col.4, lines 47-bottom; col.5, lines 1-4).

In regard to claims 4 and 32, applicant's attention is directed to Fig.2A tracing (f) which shows the AS pulse ramping up during a square wave temporal envelope (e).

In regard to claims 8, 9, and 35, the device measures right ventricular (RV) "diastolic absolute pressure" (col.4, line 64) which presumably encompasses "end diastolic pressure".

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In regard to claims 11 and 49, the PQRS complex is sensed and the AS pulse is synchronized to follow it.(col.8, lines 48-53).

In regard to claim 12, 22, 40, 41, and 49, an AS delay is calculated. See Fig.2A tracing (d).

In regard to claims 14, 23, and 44, the AS pulses occur between pacing pulses. See Fig.2A tracings (a) and (f).

In regard to claim 20, the AS pulses may be applied either epicardially (on the heart's external surface) or internally (Fig.4).

In regard to claim 21, the AS electrodes appear to be unipolar.

In regard to claim 36, can housing **118** is a reference electrode (col.10, lines 4-5) for AS electrodes **128,130** (Fig.4).

In regard to claims 39 and 42, applicant's attention is directed to Fig.4, sensing circuit **360** and its attached atrial and ventricular sensing electrodes **120, 122, 128, and 130**.

In regard to claim 51, applicant's attention is directed to the pacer's control circuits **304, 330, and 366** (Fig.4) and to memory circuits **310, 312, and 314**.

11. Claims 1, 15, 19, 26, 27, 30, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Kieval '079 (Applicant's prior art).

The Kieval '079 patent, also cited by the applicant as prior art, also describes an implantable Anodal Stimulation (AS) device similar to that described for the Kieval '464 patent

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(above), however, it is used in conjunction with a defibrillator circuit (Fig.3) for treating arrhythmias.

In regard to claim 15, applicant's attention is directed to Fig.7.

In regard to claims 19 and 27, applicant's attention is directed to the Abstract (lines 5-7) which recites that the AS pulse is generated and applied to the heart in order to inhibit cell activation to prevent arrhythmias.

In regard to claim 45, applicant's attention is directed to Figs. 2 and 3 which show these features.

***Allowable Subject Matter***

12. Claims 3, 5, 6, 10, 13, 15, 28, 29, 31, 33, 34, 38, 43, 48, 50, and 58-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 16, 17, 24, 25, 46, 47, and 52-57 are allowed.

14. The following is a statement of reasons for the indication of allowable subject matter:

Claims 16, 17, 46, and 47, as amended, recite method steps wherein the non-excitatory pulses are used for inhibiting the propagation of action potentials across the heart during surgery.

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Since none of the prior art references of record show or teach applying cardiac stimulation pulses for this purpose, the Examiner deems these claims to be allowable.

Claims 24 and 25, as amended, recite method steps used in modifying heart activation behavior in order to counteract arrhythmias including the inventive step of “changing the refractory period” of a heart segment (claim 24) and “reversibly blocking” the activation of a heart segment to obtain a “desired change” in the activation profile of a portion of the heart. Unable to find these features in the prior art, the Examiner also deems these claims to be allowable.

Claims 52 and 55 recite a method and corresponding apparatus for modifying activity of the heart including “providing one implantable light source” for generating therapeutic pulses of light. The Examiner could find no implantable defibrillators or pacers having a “light source” for providing therapy pulses to a patient.

Claims 53 and 56 describe a method and corresponding apparatus for modifying the activity of a heart as in claims 52 and 55 above, but substituting a “means for irradiating” using RF frequency radiation for “light source” to treat the patient. Again, since the Examiner could find no means of this type for generating radiation signals meeting applicant’s claimed frequency of pulses, these claims are deemed to be allowable.

Claims 54 and 57 describe a method and corresponding apparatus for applying a non-excitatory electric field to both a first and a second chamber of the heart to force the chambers to contract. The applicant’s claims state that the force of contraction is stronger in the second



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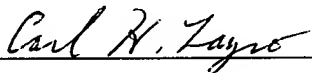
chamber than in the first. The Examiner could find no prior art relating the use of "non-excitatory" electric fields in this manner; as a result, these claims are also deemed to be allowable.

***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on M-F from 8:30 AM to 5:00 PM. A voice mail message may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef, can be reached on (703) 308-3256. The current fax number for this Group is (703) 308-3588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.



**Carl H. Layno**  
**Patent Examiner**, AV3737

CHL  
3/29/00